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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/304,859	05/04/99	BERD	D 1225/1E251-U

HM12/0901

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EXAMINER	
HUNT, J	
ART UNIT	**PAPER NUMBER**
1642	4

DATE MAILED: 09/01/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/304,859	Berd, David
Examiner	**Group Art Unit**
Jennifer Hunt	1642

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-23 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-23 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☒ The specification is objected to by the Examiner.

☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The request for priority based on a provisional application must be entered under 35 U.S.C. 119(e).

Specification

2. The disclosure is objected to because of the following informalities:

There must be a brief description which corresponds to each labeled figure (ie:14 A,B).

Appropriate correction is required.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman,* 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi,* 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum,* 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of Berd (US #5,290,551), in view of Elliot et al. (US #5,478,556). Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claim 1 of US #5,290,551 recites a composition which is a tumor cell extract wherein the tumor cells are melanoma cells. The extract is conjugated to a hapten, the same tumor type as the patient's tumor, not allogenic to said patient and incapable of growing in the patient's body after injection. Claim 2 of '551 recites a method of treating melanoma comprising administering cyclophosphamide, followed by a therapeutically effective amount of the vaccine of claim 1. The disclosure teaches a therapeutically effective amount that includes administration of the vaccine more than 6 times (column 4, line 65-66 and column 5, line 1-11), administration of a 300mg/M^2 dose of cyclophosphamide prior to vaccination (column 4, line 60), a dosage of tumor cells including 10 X 10^6 cells, which is "about" 7.5 X 10^6. (column 3, line 37), vaccination protocols which sensitize patient to the hapten prior to vaccination (column 5, line 52), vaccination protocols which do not sensitize patient to the hapten prior to vaccination (column 4, example 1) and that the effective amount is indicated by infiltration of the tumor by activated T lymphocytes (column 3, line 67-68). All of the treatments are administered to human patients.

With regard to claims 9-10 and 20-21 of applicant's invention, claim 1 of '551 specifically recites use of a hapten selected from the group comprising dinitrophenyl....etc.

With regard to claims 11-12 and 22-23 of applicant's invention, claim 1 of '551 specifically recites administration with an adjuvant, wherein the adjuvant is *Bacille Calmette-Guerin.*

Berd fails to teach weekly injections or administration of cyclophosphamide only prior to the first dose of the vaccine.

Vaccination protocols comprising weekly booster injections of inactivated autologous tumor cell extract, and administration of cyclophosphamide prior to the first injection is known in the art, as set forth by Elliot (US # 5,478,556). Therefore it would have been *prima facie* obvious to one of ordinary skill in he art at the time the invention was made to administer weekly injection of the composition disclosed in Berd, and to administer cyclophosphamide prior to the first injection because weekly boosters and administration of cyclophosphamide prior to the first injection were well known vaccine protocols, as taught in Elliot et al.

Therefore all of the applicant's claims are obvious over the claims of US 5,290,551 and thus are rejected under the judicially created doctrine of obviousness-type double patenting.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-23 are unclear in their recitation of a "therapeutically effective amount". The metes and bounds of a therapeutically effective amount cannot be determined. The disclosure is not consistent in it's definition of a therapeutically effective amount. In page 6, 3rd paragraph, the disclosure teaches that T-cell infiltration of the tumor is sometimes associated with tumor cell destruction. On page 10, in the first paragraph of the detailed description of the invention, the meaning of an anti-tumor response is detailed, including infiltration of the tumor by T-cell lymphocytes. An anti-tumor response which does not result in the destruction of tumor cells would not be therapeutic. Thus the definition in the specification and the recitation of the claims are contradictory and confusing.

Claims 12 and 23 are unclear in that they fail to define QS-21. The precise composition of QS-21 cannot be determined from the claims as recited, or from the disclosure.

Claims 16, and 18-23 are improper because they fail to define the meaning of "c.e.". It is not possible to determine the meaning of "c.e." as recited.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berd (US# 5,290,551), in view of Elliot et al. (US #5, 478, 556).

'551 teaches a composition and method of inducing an anti-tumor response comprising administering the composition, in which the composition is a tumor cell extract wherein the tumor cells are melanoma cells. The tumor cell extract is conjugated to a hapten, the same tumor type as the patient's tumor, not allogenic to said patient and incapable of growing in patient's body after injection. This composition was administered more than 6 times. (col 4, lines 65-66 and col 5, lines 1-11) Prior to vaccination, patients were administered 300mg/M2 of cyclophosphamide. (Col 4, line 60) A dosage including 10 X 10^6 tumor cells was used, which is "about" 7.5 X 10^6 cells. (column 3, line 37) The hapten is dinitrophenyl and is administered with the adjuvant Bacillus Calmette-Guerin. (col 5, lines 54-57) '551 teaches methods in which the patients is first sensitized to the hapten (col 5, line 52), and methods in which the patient is not first sensitized to the hapten. (col 4, example 1) The treatment is administered to human patients. The anti-tumor response induced is tumor infiltration by activated T lymphocytes. (Col 3, lines 67-68) '551 does not teach weekly administration of the composition, or administration of cyclophosphamide only prior to the first dose of the vaccine.

'556 teaches administration of an autologous tumor cell extract vaccine at weekly intervals, as well as a single dose of cyclophosphamide prior to administration of only the first vaccine. (see vaccine protocol, col 4)

Vaccination protocols comprising weekly booster injections of inactivated autologous tumor cell extract is known in the art, as set forth by Elliot et al. Therefore, it would have been *prima facie* obvious to one of skill in the art at the time the invention was made to administer weekly injections of the composition disclosed in Berd, because weekly injections were well known vaccine protocols, as taught by Elliot et al.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Hunt whose telephone number is (703) 308-7548. The examiner can normally be reached Monday through Friday 6:30am to 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell can be reached at (703) 308-4310. The fax number for the group is (703) 305-3014 or (703) 308-4242.

Communications via internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [**paulahutzell@uspto.gov**].

All internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists the possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist, whose telephone number is (703) 308-0196.

Jennifer Hunt

August 30, 1999

Yvonne Eyler

Yvonne Eyler
Patent Examiner